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10/713,479	11/14/2003	Timothy Z. Liu	ABIOS.035A	1204

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EXAMINER
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CROW, ROBERT THOMAS

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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12/18/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	Application No. 10/713,479	Applicant(s) LIU ET AL.	
	Examiner Robert T. Crow	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 14-30, 32-35 and 46 is/are pending in the application.
- 4a) Of the above claim(s) 19-30 and 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-18, and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1634

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 September 2007 has been entered.

### *Status of the Claims*

2. This action is in response to papers filed 26 September 2007 in which claim 1 was amended, no claims were canceled, and new claim 46 was added. All of the amendments have been thoroughly reviewed and entered.

The interview summary is acknowledged and the interview record is complete.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-12, 14-18 and 46 are under prosecution.

### *Information Disclosure Statement*

3. The Information Disclosure Statement filed 22 August 2007 is acknowledged. The International Search Report has been considered but has been lined through because there is no publication date. See 37 CFR 1.98.

Art Unit: 1634

*Claim Objections*

4. Claim 46 is objected to because of the following informalities: claim 46 recites the limitation "a light emitting diodes" in line 10. This appears to be a typographical error. Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4-5 and 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 are each indefinite because claims 4 and 5 each further limit the target nucleic acid, which is not part of the instantly claimed apparatus. It is therefore unclear how the target nucleic acid defines a structural limitation of the apparatus because the target nucleic is not part of the apparatus as claimed.

Claim 7 is vague and indefinite in the recitation "greater than about" in line 2 of claim 7. The phrase "greater than" typically indicates a minimum point; however, the phrase "greater than" is controverted by the term "about," which implies that values above and below the indicated amount are permitted. Therefore, the juxtaposition of these two terms makes it unclear what minimum number of probe elements is encompassed by the claim.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1634

8. Claims 1-10 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Blackburn et al (U.S. Patent No. 6,264,825 B1, issued 24 July 2001).

Regarding claims 1, 9 and 14, Blackburn et al teach an apparatus for detecting a target nucleic acid. In a single exemplary embodiment, Blackburn et al teach a support in the form of a substrate comprising an electrode (column 14, lines 40-55). The electrode has a detection probe for a target nucleic acid attached thereto (Figure 4a and column 4, lines 5-38). The probe is a nucleic acid having a sequence complementary to the target nucleic acid (column 4, lines 5-38). The apparatus further comprises a photoelectrochemical label in the form of a ruthenium complex with bipyridyl ligands (i.e., claim 9; column 81, lines 35-47) as a hybridization indicator (column 58, lines 35-57); the label is thus selective for doubled stranded (i.e., hybridized) nucleic acids because it detects hybridization. Blackburn et al also teach a sacrificial reductant contacting the nucleic acid probe; namely, ethylenediaminetetraacetic acid (EDTA) is added to the mixture in the apparatus (i.e., claim 14; column 18, lines 19-25), and thus contacts the nucleic acid probe. Blackburn et al teach the apparatus further comprises an electric light source; namely, and electronic light source (column 15, lines 30-40), wherein the light source initiates the photoelectrochemical label (column 80, line 66-column 81, line 6), and photoelectrochemistry is detected (column 81, line 55-column 82, line 8). The apparatus also comprises a data collection controller for measuring a current at the electrode (column 80, lines 40-55 and column 82, lines 6-25).

Regarding claim 2, Blackburn et al teach the apparatus of claim 1, wherein the nucleic acid probe comprises DNA; namely, the capture probe is a nucleic acid (column 40, lines 34-40), and the nucleic acid is DNA (column 9, lines 10-30).

Regarding claim 3, Blackburn et al teach the apparatus of claim 1, wherein the nucleic acid probe comprises RNA; namely, the capture probe is a nucleic acid (column 40, lines 34-40), and the nucleic acid is RNA (column 9, lines 10-30).

Art Unit: 1634

Regarding claim 4, Blackburn et al teach the apparatus of claim 1, wherein the target nucleic acid sequence comprises a DNA sequence; namely, the target is a DNA sequence (column 61, lines 17-48).

Regarding claim 5, Blackburn et al teach the apparatus of claim 1, wherein the target nucleic acid sequence comprises a RNA sequence; namely, the target is a RNA sequence (column 61, lines 17-48).

Regarding claims 6-7, Blackburn et al teach the apparatus of claim 1, wherein the support comprises an array of nucleic acid probe elements; namely, the array comprises about 10 to about 100 electrodes having probes thereon (column 24, lines 15-30), which are interpreted as the probe elements.

Regarding claim 8, Blackburn et al teach the apparatus of claim 1, wherein the electrode comprises gold (column 15, lines 40-60).

Regarding claim 15, Blackburn et al teach the apparatus of claim 1, further comprising an optical scanner for scanning the support; namely, the device comprises an optical fluorescence scanner (column 80, lines 40-55 and column 81, lines 15-21).

Regarding claim 16, Blackburn et al teach the apparatus of claim 1, further a fluid handling system for the support; namely, the apparatus comprises electrodes and particles to control laminar and turbulent flow (column 21, line 60-column 22, line 19), which modulates the flow of fluid in the apparatus.

It is noted that a review of the specification yields no limiting definition of a "fluid handling system;" thus, the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "fluid handling system" (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1])).

Regarding claim 17, Blackburn et al teach the apparatus of claim 1, further comprising a temperature control system for the support (column 15, lines 30-40)

Art Unit: 1634

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 11-12, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn et al (U.S. Patent No. 6,264,825 B1, issued 24 July 2001) in view of Dabiri et al (U.S. Patent No. 5,871,628, issued 16 February 1999).

Regarding claims 11-12, Blackburn et al teach the apparatus for detecting a target nucleic acid of claim 1. In a single exemplary embodiment, Blackburn et al teach a support in the form of a substrate comprising an electrode (column 14, lines 40-55). The electrode has a detection probe for a target nucleic acid attached thereto (Figure 4a and column 4, lines 5-38). The probe is a nucleic acid having a sequence complementary to the target nucleic acid (column 4, lines 5-38). The apparatus further comprises a photoelectrochemical label in the form of a ruthenium complex with bipyridyl ligands (column 81, lines 35-47) as a hybridization indicator (column 58, lines 35-57); the label is thus selective for double stranded (i.e., hybridized) nucleic acids because it detects hybridization. Blackburn et al also teach a

Art Unit: 1634

sacrificial reductant contacting the nucleic acid probe; namely, ethylenediaminetetraacetic acid (EDTA) is added to the mixture in the apparatus (i.e., claim 14; column 18, lines 19-25), and thus contacts the nucleic acid probe. Blackburn et al teach the apparatus further comprises an electric light source; namely, and electronic light source (column 15, lines 30-40), wherein the light source initiates the photoelectrochemical label (column 80, line 66-column 81, line 6), and photoelectrochemistry is detected (column 81, line 55-column 82, line 8). The apparatus also comprises a data collection controller for measuring a current at the electrode (column 80, lines 40-55 and column 82, lines 6-25).

Blackburn et al do not teach the light source is a laser (i.e., claim 11) that radiates visible light (i.e., claim 12). Thus, Blackburn et al teach a base apparatus that differs from the instantly claimed apparatus because Blackburn et al do not teach lasers with light in the visible range.

However, Dabiri et al teach a system for detecting nucleic acids in an array; namely, a system for DNA sequencing using a capillary array (Abstract) comprising electrodes (column 3, lines 65-67) and a laser light source (i.e., claim 11). The laser emits in the visible range (i.e., claim 12); namely, about 488 and 514 nm, which has the added advantage that the laser provides frequencies compatible with a wide variety of fluorescent dyes (column 7, lines 30-36). Thus, Dabiri et al teach the known technique of using a laser that radiates visible light.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus comprising a light source of Blackburn et al with a laser as taught by Dabiri et al with a reasonable expectation of success. The modification would result in a laser (i.e., claim 11) that radiates visible light (i.e., claim 12). The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of having a light source providing frequencies compatible with a wide variety of fluorescent dyes as explicitly taught by Dabiri et al (column 7, lines 30-36). In addition, it would have been obvious to the ordinary artisan that the known technique of using the light source of Dabiri et al could have been applied to the apparatus of Blackburn et al with predictable results because the light



Art Unit: 1634

source of Dabiri et al predictably results in a light source suitable for use in array-based nucleic acid assays.

Regarding claim 46, Blackburn et al teach an apparatus for detecting a target nucleic acid. In a single exemplary embodiment, Blackburn et al teach a support in the form of a substrate comprising an electrode (column 14, lines 40-55). The electrode has a detection probe for a target nucleic acid attached thereto (Figure 4a and column 4, lines 5-38). The probe is a nucleic acid having a sequence complementary to the target nucleic acid (column 4, lines 5-38). The apparatus further comprises a photoelectrochemical label in the form of a ruthenium complex with bipyridyl ligands (i.e., claim 9; column 81, lines 35-47) as a hybridization indicator (column 58, lines 35-57); the label is thus selective for doubled stranded (i.e., hybridized) nucleic acids because it detects hybridization. Blackburn et al also teach a sacrificial reductant contacting the nucleic acid probe; namely, ethylenediaminetetraacetic acid (EDTA) is added to the mixture in the apparatus (column 18, lines 19-25), and thus contacts the nucleic acid probe. Blackburn et al teach the apparatus further comprises an electric light source; namely, and electronic light source (column 15, lines 30-40), wherein the light source initiates the photoelectrochemical label (column 80, line 66-column 81, line 6), and therefore is incident to at least a portion of the electrode, and wherein photoelectrochemistry is detected (column 81, line 55-column 82, line 8). The apparatus also comprises a data collection controller coupled to the electrode operable to measure a current at the electrode (column 80, lines 40-55 and column 82, lines 6-40).

Blackburn et al do not teach the light source is a laser. Thus, Blackburn et al teach a base apparatus that differs from the instantly claimed apparatus because Blackburn et al do not teach lasers.

However, Dabiri et al teach a system for detecting nucleic acids in an array; namely, a system for DNA sequencing using a capillary array (Abstract) comprising electrodes (column 3, lines 65-67) and a laser light source, which has the added advantage that the laser provides frequencies compatible with a wide variety of fluorescent dyes (column 7, lines 30-36). Thus, Dabiri et al teach the known technique of using a laser that radiates visible light.

Art Unit: 1634

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus comprising a light source of Blackburn et al with a laser as taught by Dabiri et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in an apparatus having the added advantage of having a light source providing frequencies compatible with a wide variety of fluorescent dyes as explicitly taught by Dabiri et al (column 7, lines 30-36). In addition, it would have been obvious to the ordinary artisan that the known technique of using the light source of Dabiri et al could have been applied to the apparatus of Blackburn et al with predictable results because the light source of Dabiri et al predictably results in a light source suitable for use in array-based nucleic acid assays.

12. Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn et al (U.S. Patent No. 6,264,825 B1, issued 24 July 2001) in view of Noblett (U.S. Patent No. 6,362,004 B1, issued 26 March 2002).

Regarding claim 18, Blackburn et al teach the apparatus for detecting a target nucleic acid of claim 1. In a single exemplary embodiment, Blackburn et al teach a support in the form of a substrate comprising an electrode (column 14, lines 40-55). The electrode has a detection probe for a target nucleic acid attached thereto (Figure 4a and column 4, lines 5-38). The probe is a nucleic acid having a sequence complementary to the target nucleic acid (column 4, lines 5-38). The apparatus further comprises a photoelectrochemical label in the form of a ruthenium complex with bipyridyl ligands (column 81, lines 35-47) as a hybridization indicator (column 58, lines 35-57); the label is thus selective for double stranded (i.e., hybridized) nucleic acids because it detects hybridization. Blackburn et al also teach a sacrificial reductant contacting the nucleic acid probe; namely, ethylenediaminetetraacetic acid (EDTA) is added to the mixture in the apparatus (i.e., claim 14; column 18, lines 19-25), and thus contacts the nucleic acid probe. Blackburn et al teach the apparatus further comprises an electric light source; namely, and

Art Unit: 1634

electronic light source (column 15, lines 30-40), wherein the light source initiates the photoelectrochemical label (column 80, line 66-column 81, line 6), and photoelectrochemistry is detected (column 81, line 55-column 82, line 8). The apparatus also comprises a data collection controller for measuring a current at the electrode (column 80, lines 40-55 and column 82, lines 6-25).

Blackburn et al do not teach machine-readable identifying indicia. Thus, Blackburn et al teach a base apparatus that differs from the instantly claimed apparatus because Blackburn et al do not teach machine-readable identifying indicia.

However, Noblett et al teach the use of microarrays comprising immobilized nucleic acids (column 1, lines 20-30) having machine readable identifying indicia (e.g., fiducials [Abstract], wherein the fiducials are scanned by a positioning system; column 6, lines 41-48) with the added advantage of allowing positioning and alignment of the substrate for spot analysis and comparison procedures (Abstract). Thus, Noblett et al teach the known technique of using machine-readable identifying indicia.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the apparatus of Blackburn et al with the machine readable identifying indicia as taught by Noblett et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in an apparatus allowing positioning and alignment of the substrate for spot analysis and comparison procedures as explicitly taught by Noblett et al (Abstract). In addition, it would have been obvious to the ordinary artisan that the known technique of using the machine readable identifying indicia as taught by Noblett et al could have been applied to the apparatus of Blackburn et al with predictable results because the machine readable identifying indicia as taught by Noblett et al predictably result in a tool used for alignment of scanning equipment during scanning of array-based assays.

Art Unit: 1634

*Response to Arguments*

13. Applicant's arguments with respect to the previous rejections of the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

*Conclusion*

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jehanne Sitton/  
Primary Examiner 1634  
12/12/2007

Robert T. Crow  
Examiner  
Art Unit 1634

